DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
New Orleans District Office
6600 Plaza Drive, Suite 400
New Orleans, LA 70127

M4179n

September 14, 2000

9/14/00

CERTIFIED MAIL - RETURN RECEIPT REQUESTED

FACILITY ID# 222869

Dan Eagar, Administrator
Bessemer Carraway dba Alabama OB/GYN
915 Medical Center Drive
Bessemer, AL 35022

Warning Letter No. 00-NSV-24

Dear Mr. Eager:

Your facility was inspected on September 8, 2000 by a representative of the State of Alabama on contract to the Food and Drug Administration. This inspection revealed that your facility failed to comply with the Quality Standards for Mammography (Standards) as specified in Title 21, Code of Federal Regulations (CFR), Part 900.12, as follows:

Level 1

Phantom QC records were missing for 12 weeks for unit 1, [redacted]. ([redacted], OTH, Room: Mammo Room

This specific deficiency appeared on the Post Inspection Report, which was mailed out to your facility by the State inspector, along with instructions on how to respond to this finding. This deficiency may be symptomatic of serious problems that could compromise the quality of mammography at your facility and potentially overexpose both patients and employees involved with mammography.

It is your responsibility to ensure adherence to each requirement of the Mammography Quality Standards Act of 1992 (MQSA) and FDA's regulations. You are responsible for investigating and determining the cause of this deficiency as identified and to promptly initiate permanent corrective action.

If you fail to properly address this deficiency, FDA may, without further notice, initiate regulatory action. Under MQSA, FDA may:

- impose civil money penalties on a facility of up to $10,000 for each failure to substantially comply with, or each day of failure to comply with the Standards.

- suspend or revoke a facility's FDA certificate for failure to comply

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- seek an injunction in federal court to prohibit any mammography activity that constitutes a serious risk to human health.

Within 15 working days after receiving this letter, you should notify FDA in writing of each step your facility is taking to prevent the recurrence of similar violations.

If your facility is unable to complete the corrective actions within 15 working days, you should state the reason for the delay and the time within which the corrections will be completed.

Your reply should be directed to Joseph E. Hayes, Compliance Officer, U.S. Food and Drug Administration, 297 Plus Park Boulevard, Nashville, Tennessee 37217, telephone 615/781-5389, extension 125. Any questions in regard to this letter or how to ensure you are meeting MQSA standards, please call **Karen Smallwood, Radiation Specialist, at 615/781-5380, extension 144.**

Sincerely,

Carl E. Draper

Carl E. Draper
Director, New Orleans District

CED:KRS:man

Cc: Richard Glass
Alabama Dept. of Public Health
Division of Radiological Health
PO Box 303017
Montgomery, AL 36130-3017

Priscilla F. Butler, MS
Director, Breast Imaging Accreditation Programs
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